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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,294	03/22/2004	Scott R. Presnell	99-106C1	2898

10117 7590 04/15/2008

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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,294	PRESNELL ET AL.	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the claim amendments filed on 2/20/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 02/20/2008 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The amendments of claim 12 and the cancellation of claims 1-11 and 13 have been made of record.

Claims 12 and 14 are pending and under examination.

Response to Arguments

Priority

The objection of disclosure is withdrawn in view of applicant's amendment of the specification to update the status of US Patent Application 09/746,375 as "now abandoned."

Objections to the Specification *– withdrawn*

The objection to the specification is withdrawn in view of Applicant's amendment to replace "######' with "WO 01/40467, filed on 12/1/2000".

The objection to the specification because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of Applicant's deletion of the embedded hyperlinks.

Claim Rejections - withdrawn

Claim Rejections - 35 USC § 101

The rejection of claims 12 and 14 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility is withdrawn in view of Applicants arguments on pages 8-9 of Response filed on

2/20/2008 that the polypeptide is associated with inflammation. However, Claims 12 and 14 remain rejected under 35 USC 112, scope of enablement for the reasons discussed below.

Claim Rejections – maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 14 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons already of record on pages 3-5 of the Office Action mailed 9/20/07 because the specification, while being enabling for a polypeptide of SEQ ID NO: 1 (Zcyto18), does not reasonably provide enablement for a method of detecting activated CD3+ T-cells in a patient suffering from inflammation, comprising: obtaining a tissue or biological sample from a patient; labeling a polynucleotide, visualizing the labeled polynucleotide in the tissue or biological sample; and comparing the level of labeled polynucleotide hybridization in the tissue or biological sample from the patient to a normal control tissue or biological sample, wherein an increase in the labeled polynucleotide hybridization to the patient tissue or biological sample relative to the normal control tissue or biological sample is indicative of activated CD3+ T-cells in the patient. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to which the invention commensurate in scope with these claims.

Applicants argue (page 9 of Response) that because the polypeptide is expressed at higher level in inflammation than control, the peptide has a utility and therefore, a method of detecting expression level in inflammation CD3+ T-cells would have utility and that the specification discloses that Zcyto18 message is strongly increased in activated CD3+ T-cells.

Applicant's arguments have been fully considered but they are persuasive in part that the polypeptide has a utility and the claimed method of detecting activated T-cells by hybridizing a labeled Zcyto18 DNA has a utility. However, a method of detecting activated CD3+ T-cells by hybridization steps as recited in claim 12 is not enabled because the polynucleotide product as produced after the first reaction of the claimed method which when incubated with a tissue or biological sample would bind to many nucleic acids. Since, claims 12 and 14 do not require any specific condition for hybridization of a tissue or biological sample, any of recited labeled nucleic acid sequence would hybridize to a large number of nucleic acid sequences. Therefore, any increase in hybridization signal as a result of increased binding of labeled Zcyto18 to nucleic acids other than Zcyto18 inflammation would not necessarily be indicative of CD3+ T-cell activation. The specification does not disclose that Zcyto18 fragments comprising nucleic acids 21-557, 57-557 and 123-557 when hybridize to any nucleic acid sequence (which is not Zcyto18), under any hybridization condition, would still be indicative of activated CD3+ T-cells in a subject suffering from inflammation.

In other words, Applicants have only demonstrated that the full-length polynucleotide of SEQ ID NO:1 can be used to identify activated CD3+ T-cells. Simply using the claimed fragments of SEQ ID NO:1 in a hybridization assay does not guarantee that the increase in hybridization signal is due to hybridizing to SEQ ID NO:1. Non-activated T-cells may also express increased levels of other polynucleotides in other circumstances. Given the instant methods, it is not clear that Applicants are able to identify an increase specifically in SEQ ID NO:1 and conclude that this hybridization is due to an activated T-cell. Therefore, it is unpredictable how one of the skill in the art can practice the instantly claimed invention and that undue experimentation would be required to practice the invention as broadly claimed.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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03 April 2008
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/Robert Landsman/
Primary Examiner, Art Unit 1647